K033970

KURARAY MEDICAL INC.

Quality Assurance Department
Kuraray Nihonbashi Bldg.
3-1-6 Nihonbashi, Chuo-ku, Tokyo 103-82541
Phone : +81-(0)3-3277-6933
Facsimile: +81-(0)3-3277-6577

MAR 2 6 2004

510(k) SUMMARY

1. Submitter

1) Name	KURARAY MEDICAL INC.
2) Address	1621 Sakazu, Kurashiki, Okayama 710-8622, Japan
3) 1. Contact person	Masaya Sasaki Dental Material Division, Kuraray Medical Inc.
2. Contact person in U.S.A.	Satoshi Yamaguchi Kuraray America Inc. 101 East 52nd Street, 26th Floor New York, NY 10022 Telephone: (212)-986-2230 (Ext.115) 1-(800)-879-1676 Facsimile: (212)-867-3543
4) Date	December 19, 2003

2. Name of Device

1) Proprietary Name	CLEARFIL PHOTO CORE PLT
2) Classification Name	Tooth shade resin material (21CFR 872.3690)
3) Common/Usual Name	Light-cured Composite Resin for Core Build Up

3. Predicate device

The predicate device is as follow;

1. CLEARFIL PHOTO CORE manufactured by Kuraray Medical Inc. (K012705)
2. CLEARFIL AP-X PLT manufactured by Kuraray Medical Inc. (K023002)

4. Description for the premarket notification

This product is classified into Tooth shade Resin Material, 21CFR Section 872.3690, because it is a device composed of materials such as bisphenol A glycidylmethacrylate (Bis-GMA) intended to restore carious or structural defects in teeth.

5. Statement of the intended use

The intended use of this device is as follows. It is the same as that of CLEARFIL PHOTO CORE (K012705).

1) Core build-up of vital or non-vital tooth

6. Statement of the technological characteristics and safety

This device is a dental composite resin restorative material. The composite resin is substantially equivalent to CLEARFIL PHOTO CORE (K012705) as the chemical composition, ingredients and intended use are the same as those of the predicate device. Also, this device is different from CLEARFIL PHOTO CORE (K012705) in that it is filled in disposable tips, but the disposable tips are substantially equivalent to those that are used in CLEARFIL AP-X PLT (K012705).

Therefore this device is substantially equivalent in safety and technological characteristics as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 26 2004

Kuraray Medical Incorporated
C/O Mr. Satoshi Yamaguchi
Kuraray America, Incorporated
101 East 52nd Street, 26th Floor
New York, New York 10022

Re: K033970
Trade/Device Name: Clearfil Photo Core PLT
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: December 19, 2003
Received: December 29, 2003

Dear Mr. Yamaguchi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033970

Device Name: Clearfil Photo Core PLT

Indications For Use:
1) Core build-up of vital or non-vital tooth

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K033970